K080964
Page 1 of 4

Fresenius Medical Care

Fresenius 2008T Hemodialysis Delivery System
"Special" 510(k) Premarket Notification

JAN 14 2009

510(k) Summary

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	920 Winter Street Waltham, MA 02451
Phone:	(781)-699-9505
Fax:	(781) 699-9635
Contact Person:	Randolph Quinn, Sr. Regulatory Affairs Specialist
Date of Preparation:	3/18/2008

B. Device Name:

Trade Name:	Fresenius 2008T Hemodialysis Machine
Common/Usual Name:	Hemodialysis Machine
Classification Name:	High Permeability Hemodialysis system

Fresenius Medical Care

Fresenius 2008T Hemodialysis Delivery System
"Special" 510(k) Premarket Notification

510(k) Summary

C. Predicate Device Name:

The Fresenius 2008T is a modified version of the Fresenius 2008K Dialysate Delivery System, which was cleared under the following premarket notification:

- Fresenius 2008K #K994267 (3/16/2000)

D. Device Description/Indications for Use:

The Fresenius 2008T represents the next genesis of the Fresenius 2008K model hemodialysis machine. Hemodialysis is prescribed by physicians for patients with acute or chronic renal failure, when conservative therapy is judged inadequate. Dialysis therapy may be intermittent or continuous.

The 2008T has the same indications for use and same intended use as the predicate device the 2008K (K994267) and is as follows:

The Fresenius 2008T is indicated for acute and chronic dialysis therapy.

E. Substantial Equivalence:

1. Is the product a device?

YES - The Fresenius 2008T is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the Fresenius 2008T is equivalent to that for the Fresenius 2008K Dialysate Delivery System and is as follows:

Fresenius 2008T - Intended Use

Fresenius 2008T is indicated for acute and chronic dialysis therapy.

Fresenius 2008K - Intended Use

Fresenius Medical Care

Fresenius 2008T Hemodialysis Delivery System
"Special" 510(k) Premarket Notification

510(k) Summary

Fresenius 2008K is indicated for acute and chronic dialysis therapy.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The Fresenius 2008T is a modified version of the Fresenius 2008K Dialysate Delivery System. The performance and technological characteristics of the Fresenius 2008T are equivalent to those of the Fresenius 2008K Dialysate Delivery System and raise no new types of safety or effectiveness questions.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Fresenius 2008T and demonstrates that it is substantially equivalent to the Fresenius 2008K Dialysate Delivery system.

F. Safety Summary

The Fresenius modified 2008T hemodialysis machine incorporates changes with regards to the user interface only and all water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines, and language options remain unchanged from the predicate device, the 2008K (K994267). A Risk Analysis has been completed and potential hazards associated with the modifications have been identified, mitigated and where applicable mitigations have been verified. All potential risks were deemed acceptable after mitigation.

G. General Safety and Effectiveness Concerns

Operators of the 2008T Hemodialysis machine must be trained to administer hemodialysis at the direction of a physician. In addition, the operator should be:

- Knowledgeable of hemodialysis methodology and relevant physiology.

Fresenius Medical Care

Fresenius 2008T Hemodialysis Delivery System
"Special" 510(k) Premarket Notification

510(k) Summary

- Proficient in healthcare procedures regarding aseptic techniques.
- Thoroughly familiar with the contents of the Operator's manual.
- Fully trained and qualified to operate this machine, and able to distinguish between normal and abnormal operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2009

Ms. Janet C. Kay
Manager, Regulatory Affairs
Renal Therapies Group
Fresenius Medical Care North America
920 Winter Street
WALTHAM MA 02451

Re: K080964
Trade/Device Name: Fresenius 2008T Hemodialysis Delivery System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Product Code: KDI
Dated: December 16, 2008
Received: December 18, 2008

Dear Ms. Kay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fresenius Medical Care

Indications for Use

510(k) Number (if known): K080964

Device Name:

Fresenius 2008T Hemodialysis Machine

Indications for Use:

Fresenius 2008T is indicated for acute and chronic dialysis therapy.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Fresenius Medical Care North America
Corporate Headquarters: 920 Winter Street Waltham, MA 02451 (781) 699-9000

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080964